5. 510(k) SUMMARY

K122788

DATE: February 17, 2012

OWNER: Northstar Healthcare Holdings
70 Sir John Rogerson's Quay
Dublin 2, Ireland

JAN 17 2013

OFFICIAL CORRESPONDENT: Michael Riordan
Operations Manager
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DEVICE NAME:

Trade Name: Textured, White, Latex, Sterile Powder Free Examination Gloves with Protein labeling Claim (50µg/dm² or Less of Water Soluble Protein)

Common Name: Patient Examination Gloves

Classification: Patient Examination Gloves

Class: Class I

Product Code: LYY

PREDICATE DEVICE(S):

Predicate 510(k)	Device Name	Indication	Clearance Date	Company
K090327	Powder Free Polymer Coated Latex Examination Gloves, Sterile, with Protein labeling Claim (50µg/dm² or Less of Water Soluble Protein)	A powder free polymer coated latex examination glove is a disposable device made of natural rubber material intended to be worn on the hand for medical purposes to provide barrier against potentially infectious materials and other contaminants.	03 Apr 2009	Wear Safe SDN, BHD

DEVICE DESCRIPTION: Textured, White, Latex, Sterile Powder Free Examination Gloves with Protein labeling Claim (50µg/dm² or Less of Water Soluble Protein)

STATEMENT OF INTENDED USE:

The Textured, White, Latex, Sterile Powder Free Examination Gloves with Protein labeling Claim (50µg/dm² or Less of Water Soluble Protein) is a Disposable device intended for medical purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

TECHNOLOGICAL CHARACTERISTICS:

The Textured, White, Latex, Sterile Powder Free Examination Gloves with Protein labeling Claim (50µg/dm² or Less of Water Soluble Protein) is substantially equivalent to the predicate device with regard to physical characteristics, design, product features, and intended use. Both gloves are made with latex using similar manufacturing processes.

Feature	Powder Free Polymer Coated Latex Examination Gloves, Sterile, with Protein labeling Claim (50µg/dm² or Less of Water Soluble Protein) K090327 Predicate	Textured, White, Latex, Sterile Powder Free Examination Gloves with Protein labeling Claim (50µg/dm² or Less of Water Soluble Protein) (Proposed)
Intended Use	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Indications for Use Statement	A powder free polymer coated latex examination glove is a disposable device made of natural rubber material intended to be worn on the hand for medical purposes to provide barrier against potentially infectious materials and other contaminants.	The sterile latex examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
Description	Sterile, powder free, examination gloves made of latex. The gloves are provided in sizes small, medium, and large.	Same
Presentation	Sterile gloves are provided in dispenser boxes.	Same
Color	White	White
Material	Latex	Same
Sterilization	Sterile	Same
Single Use	Yes	Same
Dimensions	Meets ASTM D3578-05	Length: Small 220mm min.; Medium, Large 230 mm min. Width: Small 80-90mm; Medium 90-100mm; Large 101-111mm Thickness: Finger 0.13 mm min.; Palm 0.11 mm min.
Physical Properties	Meets ASTM D3578-05	Before aging/after aging Elongation 650% 500% Tensile Strength 18MPa 14MPa
Freedom from Pinholes	Meets ASTM D5151-06	Same
Residual Powder	Meets ASTM D6124-06	Same
Protein Level	Meets ASTM D5712-10	Same

Biocompatibility Tests	Passes Primary Skin Irritation in Rabbits Passes Guinea Pig Maximization	Same Same
Sterilization	Radiation dose of 25 kGy.	Same

ASSESSMENT OF NONCLINICAL DATA:

Characteristic	Standard	Device Performance
Dimension	ASTM Standard D3578	Meets
Physical Properties	ASTM Standard D3578	Meets
Freedom from Pinholes	21 CFR 800.20; ASTM D5151	Meets
Powder Residual	ASTM Standard D6124	Meets Results generated values below 2mg of residual powder
Protein Level	ASTM Standard D5712	Meets Results generated values below 50 mcg/gm
Biocompatibility	Primary Skin Irritation in rabbits (ISO 10993-10)	Gloves are non-irritating
	Dermal Sensitization in the guinea pig (ISO 10993-10)	Gloves do not display any potential for sensitization

CONCLUSIONS:

The Latex Sterile Powder Free Examination Gloves meet the requirements of established standards ASTM D3578-05, ASTM D5712-10, ASTM D5151-06, ASTM D6124-06 and ISO 10993-10.

Based on the comparison of intended use, design, materials and performance, the Latex Sterile Powder Free Examination Gloves are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 17, 2013

Northstar Healthcare Holdings
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, IL 60062

Re: K122788
Trade/Device Name: Textured, White, Latex, Sterile Powder Free Examination Gloves with Protein Labeling Claim (50μg/dm^2 or Less of Water Soluble Protein)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: November 27, 2012
Received: January 4, 2013

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

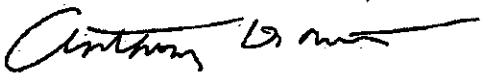
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122788

Device Name: **Textured, White, Latex, Sterile Powder Free Examination Gloves with Protein labeling Claim (50µg/dm² or Less of Water Soluble Protein)**

Indications for Use: The examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

AND/OR

Prescription Use_____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use __X__
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Elizabeth F. Claverie
Concurrence of CDRH, Office of Device Evaluation (ODE)
2013.01.16 15:21:39 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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